CURRICULUM VITAE

Joseph L. Moore, Jr.

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CLINICAL RESEARCH EXPERIENCE

- 12+ years of experience as a Data Manager on clinical research studies for indications including Diabetes Type I/II, Obesity, Stroke, ADHD, Alzheimer's disease, Chronic Obstructive Pulmonary Disease, Depression, Huntington's Disease, Insomnia, Jet Lag, Narcolepsy, Restless Leg Syndrome, Sleep Apnea.
- Specializing in data management with a focus on Digital Health including:
    - Electronic Diaries (ePRO)
    - Continuous Glucose Monitoring (CGM, FGM)
    - Data analytics and visualizations with SAS
    - Certified SAS programmer
    - Data Flow between Clinical Data Repositories, Amazon Web Services (AWS S3), Azure Storage Blobs
    - Software as a Medical Device (SaMD)
    - Decentralized Clinical Trials
- Data Management experience working in both United States and EU Pharmaceutical markets having worked in CROs and Pharmaceutical companies in New York, New Jersey, and Denmark
- Lead role as a Data Manager or Project Manager on more than 70 Phase I-IV Clinical Trials ranging from single-site studies to larger multi-site and international trials including a fully virtual clinical research project.
- Served as Project Lead for both EKG and EEG Core labs in a CRO environment.
- Experienced in all aspects of Clinical Trial Data Management activities from study initiation to database lock including eDiary development, App development, CRF and eCRF design, eCRF building and programming, Integration of EDC, IVRS, and OC, Data Management Plans, Database design, Edit Check Programming, User Acceptance Testing, Trial Validation Plans, Safety Reports, Software validation, Site and Coordinator training, Dataset QC and electronic data transfers, Query Resolution and Reconciliation, SOP development, lead with efficiency improvement processes.
- Analyzed, Managed, and/or collected data for Labs, Holter Monitoring, PSG, MWT, EEG, ECG, SIT, PVT, CGM, FGM, and Actigraphy.
- EDC Experience: Inform, Rave, OpenClinica

Relevant Skills

- Ability to focus on project-specific details while multi-tasking
- Work effectively under pressure; able to meet short and long-term deadlines with excellent prioritization and problem-solving skills
- Comfortable communicating, either verbally or written, with all levels of clinical research team members from study technicians, coordinators, managers, programmers, statisticians, regulatory, and data personnel.
- Proficient in Microsoft Office Suite, Windows & Apple Systems
- Proficient SAS programmer
- Intermediate Proficiency in German, Danish, and American Sign Language (ASL)
- Dual U.S./German Citizen with Both US and EU (German) Passports

EMPLOYMENT

Novo Nordisk A/S. Insulin and Devices, Copenhagen, Denmark 12/2015 - Current
Senior Data Manager

- Managing both Phase 1 and later Phase 2-4 EDC trials running on Inform and OpenClinica

- Programming automated reports and checks of SDTM and Raw data files using SAS.
- Key DM contact in the development of an in-house eDiary solution for an entire clinical program of 6 trials.
- Initiating Clinical Trials and Studies using new technologies in Insulin Care such as Flash Glucose Monitoring and Continuous Glucose Monitors

Lundbeck A/S. Biometrics, Copenhagen, Denmark 05/2014-11/2015
Clinical Data Manager/Electronic Data Process Manager

- Data Management with an emphasis on electronic data transfer, handling, and data loading
- Expanded Data Manager role to include Vendor selection, oversight, and management
- Worked in a specialist working group to identify methods for simplifying laboratory data and defining laboratory standards

Novo Nordisk A/S. Insulin and Diabetes Outcomes, Copenhagen, Denmark 10/2013-03/2014
Trial Data Manager

- Creation of trial documentation and trial tool systems (IVRS, EDC, OC) as well as integrating data flow between systems
- Design of eCRF mockups, and Edit Check Specifications for InForm EDC 4.6
- Creation of Blinding Plans, Safety report specifications and reports, Titration requirements and reports, Trial Validation Plans, Safety Reports, and Laboratory Specifications.
- Setup and UAT testing of all study startup electronic systems and electronic reports

Forest Laboratories, Inc. Clinical Data Management, Jersey City, NJ 03/2013-10/2013
Sr. Clinical Data Manager

- Protocol review and CRF design (paper and\or eCRF)
- Write/test edit checks and design edit check specifications
- Prepare Data Management Core Documents including EDC (InForm) design specifications, EDC UAT test documentation, Data Management Plans, Data Transfer Specifications
- Data Management processes including Query tracking and resolution, SAE reconciliation between clinical and safety databases, database lock activities, timelines, and milestone development

Clinilabs, Inc., Data Services, New York, NY 07/2012-07/2013
Sr. Data Manager/Project Manager

- Perform all DM-related activities, as needed, with increased autonomy and responsibility of supervision for other Project Managers and Data Coordinators.
- Training and oversight of Clinical Research Unit staff (CRCs and Research Assistants) in good data collection practices, protocol and regulatory binder reviews, study workflows.
- CRO Point of Contact: the creation of Data Transfer Agreements, Database design, Data Cleaning, and validation of propriety software applications
- Manage EEG and EKG core lab specializing in Holter Monitoring, EKG telemetry, High-Density EEG.

Clinilabs, Inc., Data Services, New York, NY 06/2008-07/2012
Data Manager/Project Manager

- Project manager for software application development projects and system validation
- Trainer for study sites, Data Management Coordinators, as well as Clinical team members on data QC, edit checks, and data handling/collecting procedures for each study
- CRF Design and Edit check specification design and build
- User Acceptance Testing (UAT) for software development projects
- Creation of documentation for data management, IT, and quality assurance procedures

Clinilabs, Inc., Data Services, New York, NY 01/2008-06/2008
Data Management Coordinator

- DM Point of Contact for vendors, clinical sites, and data Core Lab DM activities
- Certifying study sites for data collection and electronic data transfer

- Protocol Outline/Protocol Reviews for data collection and pipelines
- Create new and/or revised data management, IT, and quality assurance procedures

Avigenics Inc. Athens, GA 04/2007-08/2007
Research Assistant

- Assisted with animal husbandry, bleeding, egg extraction, semen collection, surgery, DNA isolation from blood, PCR prep, and hematocrit readings.
- Followed Good Manufacturing Practices (GMP) and IACUC training on risks of working with small animals.

University of Georgia Biology and Physiology Labs, Athens, GA 08/2004-08/2006
Graduate Teaching Assistant

- Taught 3 sections a week of Introduction to Biology Lab/Physiology | graded, prepared, and presented lecture material and quizzes/exams for 60+ students/semester
- Taught basic laboratory skills and equipment handling techniques including:
  - DNA Isolation, Gel Electrophoresis, Statistical analysis, Spectrometry, basics of quantitative vs. qualitative analysis

University of Georgia, Athens, GA 08/2000-05/2004
Undergraduate Researcher

- **2003-2004:** Microarray analysis of gene expression for wild-type sorghum and a mutant sorghum strain lacking a functional phytochrome B protein.
- **2002-2003:** Implemented computer programming techniques for bioinformatics applications to relational database systems on the Oracle platform, using Visual Basic and SQL.
- **2001-2002:** Used various bioinformatics programs such as Consed, Phred/Phrap, and Polyphred to discover single nucleotide polymorphisms (SNPs), micro-satellites, and alternate splicing events.
- **2000-2001:** Learned basics of GLP growing bacterial colonies as well as isolating and purifying cDNA libraries. Performed thermal cycling and PCR techniques to prep DNA for sequencing and BLAST sequences against NCBI GenBank Databases.

ACADEMIC TRAINING

SAS Certified Base Programmer for SAS 9 (CBP)
Credential ID: V2K9FVG1L1EQ1Z9P

Københavns Universitet – Copenhagen University
Master of Industrial Drug Development 2021 - *In progress*
Expected completion 2023

Pennsylvania State University
Graduate Certificate in Applied Statistics 2018 - 2020

University of Georgia, Athens, GA 2004
Two and a half years of Masters Studies
Biochemistry and Molecular Biology

B.S Biochemistry and Molecular Biology 2000 - 2004
Minor Field: Music - Violoncello

Certified Polysomnographic Technologist (CPSGT) 2010
Credential ID: 90022991
Expired: 2014

Clinical Training/Past Certifications: HIPPA, 21 CFR part 11, GxP (GLP, GMP, GCP, GDP) InForm, Basic Life Support (BLS), and Certified Polysomnographic Technologist (CPSGT), SAS Programming